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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/062,811	01/31/2002	Thomas Victor Magee	PC11895A	5184

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EXAMINER

AULAKH, CHARANJIT

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 05/16/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
10/062,811

Applicant(s)  
Magee, T.V. et al.

Examiner  
CHARANJIT AULAKH

Art Unit  
1625

— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Dec. 27, 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 9, 17, and 19-22 is/are rejected.
- 7) ☒ Claim(s) 2-8, 10-16, and 18 is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 3 6) ☐ Other:

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### **DETAILED ACTION**

1. According to paper no. 7 filed on Dec. 27, 2002, the applicants have elected group I ( example 1d as species ) without traverse in response to restriction requirement for further prosecution.
2. Claims 1-22 are pending in the application.

### ***Specification***

3. The abstract of the disclosure is objected to because it is too long. Correction is required. See MPEP § 608.01(b).

### ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 20 and 21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating diseases such as asthma or COPD, does not reasonably provide enablement for treating all other unrelated diseases such as rheumatoid arthritis, psoriasis, pulmonary hypertension, central nervous system disorders, liver injury, leukemia, HIV etc. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The following eight different factors ( see Ex parte Foreman, 230 USPQ at 547; Wands, In re, 858.F.

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2d 731, 8 USPQ 2d 1400, Fed. Cir. 1988 ) must be considered in order for the specification to be enabling for what is being claimed:

Quantity of experimentation necessary, the amount of direction or guidance provided, presence or absence of working examples, the nature of invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability and the breadth of claims. In the instant case, the specification is not enabling based on at least four of the above mentioned eight factors such as quantity of experimentation necessary, the amount of direction or guidance provided, presence or absence of working examples and the state of the prior art.

The instant compounds are inhibitors of PDE4 isozyme and therefore, they will have utility in treating diseases where PDE4 isozyme is involved in their etiology such as asthma and COPD.

There is no teaching in the specification or prior art that PDE4 isozyme is implicated in the etiology of all other diseases mentioned in claims 20 and 21 such as rheumatoid arthritis, psoriasis, pulmonary hypertension, central nervous system disorders, liver injury, leukemia, HIV etc. There is no guidance or direction provided in the specification and furthermore, there are no working examples to show how the instant compounds having inhibitory effect on PDE4 isozyme will have utility in treating all these unrelated disorders where PDE4 isozyme is not known to be involved in their etiology. In absence of such teachings and guidance, it would require undue experimentation to demonstrate the effectiveness of hundreds of thousands of instant compounds in treating all other hundreds of diseases other than asthma and COPD.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 17, 19 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 17, at the end of each compound, the applicants mention ---of formula (6.0.30)----.

However, there is no formula present in the claim. The applicants are suggested to delete this term in all the compounds.

In claim 19, the applicants are suggested to delete the term ---use in --- before treating in line 1 and furthermore, insert ----administering----- after comprising in line 3.

In claim 22, the term --combination--- is vague since the purpose of the combination is not clear. The applicants are suggested to direct the claim either to a pharmaceutical composition comprising the combination or a method of treating using this combination.

### *Claim Rejections - 35 USC § 102*

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1, 9 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Hitzel et al. ( U.S. Patent no. 4,181,658, cited on applicants' form 1449 ).

Hitzel discloses certain Nicotinamido-N-benzoic acid derivatives and pharmaceutical compositions containing these compounds. The compounds and pharmaceutical compositions

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containing them ( see claims 1-4 ) disclosed by Hitzel anticipate the instant claims when w represents O, m is 0 , A represents formula (1.1.1 ) and R7 represents H in the instant compounds of formula (1.0.0).

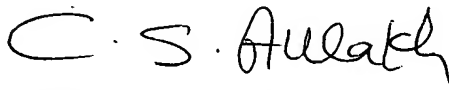
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9. Claims 1-16 and 18-22 are objected since they contain non-elected subject matter. The applicants are suggested to amend the claims to delete non-elected subject matter since the election was without traverse.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chana Aulakh whose telephone number is (703) 305-4482. The examiner can normally be reached on " Monday-Thursday " from 7:30 A.M. to 6:00 P.M.

If the attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Alan Rotman, can be reached on (703) 308-4698. The fax number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group's receptionist whose telephone number is (703) 308-1235.



CHARANJIT S. AULAKH

PRIMARY EXAMINER